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PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Mark G. Schrom, et al.  
Serial No.: 09/500,213  
Filed: February 8, 2000  
For: NEUROSTIMULATING LEAD  
Group No.: 3762  
Examiner: George Robert Evanisko

**MAIL STOP APPEAL BRIEF - PATENTS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPEAL BRIEF**

The Appellant has appealed to the Board of Patent Appeals and Interferences from the decision of the Examiner dated February 23, 2005, finally rejecting Claims 43-56, 62-64, 66-67 and 69-78. The Appellant filed a Notice of Appeal on May 23, 2005. The Appellant respectfully submits this brief on appeal with the appropriate statutory fee.

**REAL PARTY IN INTEREST**

This application is currently owned by Micronet Medical, Inc. as indicated by an assignment recorded on May 2, 2000, in the Assignment Records of the U.S. Patent and Trademark Office at Reel 010797, Frame 0789.

**RELATED APPEALS AND INTERFERENCES**

There are no known prior or pending appeals, interferences or judicial proceedings that are related to, will directly affect, be directly affected by, or have a bearing on the Board's decision in this pending appeal.

**STATUS OF CLAIMS**

Claims 43-56, 62-64, 66-67 and 69-78 have been rejected pursuant to a final Office Action dated February 23, 2005. Claims 1-42, 57-61, 65 and 68 have been cancelled. A copy of the claims is provided in the Appendix.

**STATUS OF AMENDMENTS**

No amendments were submitted and refused entry after issuance of the final Office Action dated February 23, 2005.

**SUMMARY OF CLAIMED SUBJECT MATTER**

Regarding independent Claim 43, a neurostimulating lead 10 includes a body member with a proximal end portion 14, a body member 12 with a wall, and a distal end portion 16. *Application: page 6, lines 22-26; Figure 1.* First 20 and second 22 conductors extend between the proximal and distal ends of the body member and are located within its wall. *Application: page 7, lines 5-6; Figure 2.* The first and second conductors are each spaced about the same distance from a longitudinal axis of the body member. *Application, Figure 2.* First and second openings 36 in the wall in the distal end portion lead to the first conductor. *Application: page 8, lines 22-26; page 9, lines 10-14; Figure 3.* A third opening 36 leads to the second conductor. *Id.* First and second conductive links 38 are located in the first and second openings to electrically connect to the first conductor. *Application: page 10, lines 6-7; Figure 4.* A third conductive link 38 is located in the third opening to electrically connect to the second conductor. *Id.*

First 28 and second 30 band electrodes are positioned at the distal end portion of the body member, proximate to its outer surface. *Application: page 7, lines 21-22; page 9, lines 24-26; Figures 1 and 3.* The first band electrode is electrically connected to the first and second conductive links. *Application: page 9, lines 26-28; Figure 3.* The second band electrode is electrically connected to the third conductive link. *Application: page 10, lines 3-4.*

Regarding independent Claim 62, a medical lead 10 includes a body member 12 with a length, a surface, and proximal 14 and distal 16 end portions. *Application: page 6, lines 22-26; Figure 1.* A first conductor 20 extends substantially the length of the body member. *Application:*

*page 7, lines 5-6; Figure 2.* First and second tunnels 36 extend from the surface to the first conductor in the distal end portion of the body member. *Application: page 8, lines 22-26; page 9, lines 10-14; Figure 3.* First and second conductive links 38 are located within the first and second tunnels, respectively, and are electrically connected to the first conductor. *Application: page 10, lines 6-7; Figure 4.* A first electrode 28 is positioned at the distal end portion of the body member and is electrically connected to the first and second conductive links. *Application: page 10, lines 6-7; Figure 4.*

A second conductor 22 extends substantially the length of the body member. *Application: page 7, lines 5-6; Figure 2.* The first and second conductors are each spaced about the same distance from a longitudinal axis of the body member. Third and fourth tunnels 36 extend from the surface to the second conductor in the distal end portion of the lead. *Application: page 8, lines 22-26; page 9, lines 10-14; Figure 3.* Third and fourth conductive links 38 are located within the third and fourth tunnels, respectively, and are electrically connected to the second conductor. *Application: page 10, lines 6-7; Figure 4.* A second electrode 30 is positioned at the distal end portion of the body member and is electrically connected to the third and fourth conductive links. *Application: page 10, lines 6-7; Figure 4.*

Regarding independent Claim 63, a medical lead 10 includes a body member 12 with a wall, and proximal 14 and distal 16 end portions. *Application: page 6, lines 22-26; Figure 1.* First 20 and second 22 conductors are located within the wall of the body member and extend substantially between the proximal and distal ends of the body member. *Application: page 7, lines 5-6; Figure 2.*

The first and second conductors are each spaced about the same distance from a longitudinal axis of the body member. *Application, Figure 2.* First 28 and second 30 band electrodes are positioned at either the proximal or distal end portion of the body member. *Application: page 7, lines 21-22; page 11, lines 3-8; Figure 1.* First and second conductive links 38 extend through the wall of the body member to electrically connect the first conductor and the first electrode. *Application: page 10, lines 6-7; page 11, lines 8-16; Figures 4 and 5.* A third conductive link extends through the wall of the body member to electrically connect the second conductor and the second electrode. *Id.*

Regarding independent Claim 67, a medical lead 10 includes a lead body 12 with an insulator. *Application: page 6, lines 22-27; Figure 1.* The lead body also has first 20 and second 22 conductors spaced substantially equidistant from a longitudinal axis of the lead body. *Application, Figure 2.* The insulator has first and second regions 36 in the distal end portion of the lead body that expose at least a portion of the first conductor. *Application: page 8, line 22, through page 9, line 4.* The first and second regions are formed by the removal of at least a portion of the insulator. *Application, page 8, lines 25-26.* The insulator also has third and fourth regions 36 in the distal end portion of the lead body that expose at least a portion of the second conductor. *Application: page 8, line 22, through page 9, line 4.* The third and fourth regions are also formed by the removal of at least a portion of the insulator. *Application: page 8, lines 25-26.*

The medical lead also has a first electrode 28 electrically connected to the first conductor through the first and second regions, and a second electrode 30 electrically connected to the second conductor through the third and fourth regions. *Application: page 10, lines 6-7; Figure 4.*

Regarding independent Claim 71, a medical lead 10 includes a lead body 12 with an insulator and first 20 and second 22 conductors. *Application: page 6, lines 22-27; page 7, lines 4-7; Figure 1.*

The first and second conductors are spaced about the same distance from a longitudinal axis of the body member. *Application, Figure 2.* The lead body has first and second tunnel regions 36 that are formed by removal of first and second portions, respectively, of the insulator from the lead body. *Application: page 9, lines 12-13; page 8, line 22, through page 9, line 4; Figure 3.* The lead body also has third and fourth tunnel regions 36 that are formed by removal of third and fourth portions, respectively, of the insulator from the lead body. *Id.*

The medical lead also has first and second conductive links 38 with at least a portion of the links positioned within the first and second tunnel regions, respectively. *Application, page 9, lines 4-7.* The first and second conductive links are electrically connected to the first conductor. *Id.* The medical lead also has third and fourth conductive links 38 with at least a portion of the links positioned within the third and fourth tunnel regions, respectively. *Application, page 9, lines 4-7.* The third and fourth conductive links are electrically connected to the second conductor. *Id.* A first band 28 is electrically connected to the first and second conductive links. *Application: page 10, lines 6-7; Figure 4.* A second band 30 is electrically connected to the third and fourth conductive links. *Id.*

Regarding independent Claim 75, a medical lead 10 includes a lead body 12 with an insulator. *Application: page 6, lines 22-27; Figure 1.* The lead body also has first 20 and second 22 conductors spaced about the same distance from a longitudinal axis of the lead body. *Application,*

*Figure 2.* The insulator has first and second openings 36 that are formed in the distal end portion of the lead body by the removal of at least first and second portions of the insulator. *Application, page 8, lines 25-26.* At least a portion of the first and second openings expose at least a portion of the first conductor. *Application: page 8, line 22, through page 9, line 4.* The insulator also has third and fourth openings 36 that are formed in the distal end portion of the lead body by the removal of at least third and fourth portions of the insulator. *Application, page 8, lines 25-26.* At least a portion of the third and fourth openings expose at least a portion of the second conductor. *Application: page 8, line 22, through page 9, line 4.*

The medical lead also has first and second conductive links 38 within the first and second openings, respectively. *Application, page 9, lines 4-7.* The first and second conductive links are electrically connected to the first conductor. *Id.* The medical lead also has third and fourth conductive links 38 within the third and fourth openings, respectively. *Application, page 9, lines 4-7.* The third and fourth conductive links are electrically connected to the second conductor. *Id.* A first band electrode 28 is electrically connected to the first and second conductive links to electrically connect it to the first conductor. *Application: page 10, lines 6-7; Figure 4.* A second band electrode 30 is electrically connected to the third and fourth conductive links to electrically connect it to the second conductor. *Id.*

**GROUND OF REJECTION**

1. Claims 43, 44, 52, 53, 62, 63, 67, 69, 71-73 and 75-78 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,796,044 to Cobian, *et al.* (“Cobian”) in view of U.S. Patent No. 4,590,950 to Iwaszkiewicz, *et al.* (“Iwaszkiewicz”).
2. Claims 43, 44, 52, 53, 62, 63, 67, 69, 71-73 and 75-78 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iwaszkiewicz*.
3. Claims 54, 66 and 70 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over *Iwaszkiewicz*.
4. Claims 45-50 and 56 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iwaszkiewicz*.
5. Claims 51, 64, 74 and 77 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iwaszkiewicz* in view of U.S. Patent No. 5,433,742 to Willis (“Willis”) or U.S. Patent No. 5,016,646 to Gotthardt, *et al.* (“Gotthardt”).
6. Claim 55 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iwaszkiewicz*.

**ARGUMENT**

**I. GROUND OF REJECTION #1**

The rejection of Claims 43, 44, 52, 53, 62, 63, 67, 69, 71-73 and 75-78 under 35 U.S.C. § 103(a) is improper and should be withdrawn.

**A. OVERVIEW**

Claims 43, 44, 52, 53, 62, 63, 67, 69, 71-73 and 75-78 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,796,044 to Cobian, *et al.* (“Cobian”) in view of U.S. Patent No. 4,590,950 to Iwaszkiewicz, *et al.* (“Iwaszkiewicz”).

**B. STANDARD**

In *ex parte* examination of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. (*MPEP* § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992)). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. (*MPEP* § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984)). Only when a *prima facie* case of obviousness is established does the burden shift to the Appellant to produce evidence of nonobviousness. (*MPEP* § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993)). If the Patent Office does

not produce a *prima facie* case of unpatentability, then without more the Appellant is entitled to grant of a patent. (*In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 U.S.P.Q. 870, 873 (Fed. Cir. 1985)).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. (*In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993)). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not based on the Appellant's disclosure. (MPEP § 2142).

**C. THE COBIAN REFERENCE**

*Cobian* discloses a medical lead having multiple coiled wire conductors extending from a proximal end to electrodes at a distal end of the lead. *See Figs. 1 and 2 of Cobian* (in particular elements 32A-32D). Each coiled wire conductor is individually insulated electrically by a respective insulative jacket or sheath. *Col. 7, lines 22-28; Figs. 2 and 3.*

Additionally, *Cobian* discloses that medical leads are typically subjected to mechanical stresses that result in degradation of the wire conductor(s) of the medical leads. *Col. 1, lines 23-35*. Over time, such degradation can cause lead fracture and, thereby, render a pacemaker or other such system inoperable. *Col. 1, lines 35-41*. A fractured lead can also damage the well-being of the patient as detailed by *Cobian*. *Id.* The degradation of a conductor of a medical lead can be accelerated due to material reactions (e.g., corrosion occurring due to contact with bodily fluids). *Col. 4, lines 34-38*. The corrosion is also accelerated by the application of electrical energy through the conductor for the pertinent medical therapy. *Id.*

Due to such issues, *Cobian* discloses that it is important to mitigate or otherwise address defects in insulative sheaths applied to wire conductors. *See e.g., col. 4, lines 24-47*. For example, *Cobian* discloses that “an inner insulative liner or sheath 27 within lumen 26 may be provided to protect conducts 32A, 32B, 32C, and 32D from nicks that might otherwise occur due to the passage of the stylet” through the lead. *Col. 8, lines 44-47*. That is, nicks in the insulative material provide an opening for body fluids and, thereby, facilitate the degradation of the conductor(s).

**D. THE IWASZKIEWICZ REFERENCE**

*Iwaszkiewicz* describes an external connection assembly for a conductor insulated by a compressible sleeve. *Abstract*. The conductor (uninsulated) is helically wound inside the insulative sleeve such that each winding (or loop) physically and electrically contacts each adjacent winding. *Col. 3, lines 25-28; Fig. 3*. Such configuration provides mechanical strength and stiffness. One or

more bridging wires are passed radially through the insulative sleeve. *Col. 5, lines 16-26; Fig. 3.* The helically wound conductor is then slid along the inside of the insulative sleeve to force the bridging wire to bend over and contact the outer surface along multiple windings of the conductor. *Col. 5, lines 31-37; Fig. 4.* Thus, the internal portion of the bridging wire lies longitudinally along several windings (or loops) of the conductor. *Figs. 2 and 4.* Similarly, a ring electrode is slid along the outer surface of the insulative sleeve in order to fold over and make electrical contact with the bridging wire. *Col. 5, line 67, through col. 6, line 3; Fig. 5c.* The ring electrode thus clamps the bridging wire between itself and the helically wound conductor, creating electrical contact between the three. *Abstract; col. 6, lines 3-8, Figs. 2 and 5c.*

*Iwaszkiewicz* incorporates a second conductor into the implantable lead using a similar helically wound conductor with a smaller coil diameter than the first conductor and separated from the first conductor by another insulative sleeve. *Col. 4, lines 29-32.* Thus, *Iwaszkiewicz* teaches two helically wound conductors, where each conductor is positioned at different distances from the longitudinal axis of the lead. In addition, *Iwaszkiewicz* teaches that this second conductor is not connected to electrodes by the method described above, but rather by prior art methods. *Col. 6, lines 9-14.*

**E. CLAIMS 43, 44, 52 and 53**

Independent Claim 43 recites a neurostimulating lead that includes:

a body member having a wall, a proximal end portion and a distal end portion;

a first conductor within the wall of the body member and extending between the proximal end portion and the distal end portion;

a second conductor within the wall of the body member and extending between the proximal end portion and the distal end portion, and wherein the first conductor and the second conductor are each spaced about the same distance from a longitudinal axis of the body member;

a first opening in the wall in the distal end portion leading to the first conductor;

a second opening in the wall in the distal end portion leading to the first conductor;

a third opening in the wall in the distal end portion leading to the second conductor;

a first conductive link within the first opening to electrically connect to the first conductor;

a second conductive link within the second opening to electrically connect to the first conductor;

a third conductive link within the third opening to electrically connect to the second conductor;

a first band electrode positioned at the distal end portion and proximate the outer surface of the body member and electrically connected to the first conductive link and to the second conductive link; and

a second band electrode positioned at the distal end portion proximate the outer surface of the body member and electrically connected to the third conductive link.

The Examiner fails to establish that the combination of *Cobian* and *Iwaszkiewicz* discloses, teaches, or suggests all the elements recited in Claim 43. Appellant submits that there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings, rather than use the inventions taught by the references themselves. Appellant respectfully suggests that the Examiner's argument is instead based upon hindsight and selective picking and choosing of specific elements/features within the references to come up with Appellant's invention. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not based on appellant's disclosure.

The Office Action mailed February 23, 2005 states that *Cobian* discloses first and second conductors equally spaced from a longitudinal axis and coupled to electrodes. Office Action, page 2.

The Office Action acknowledges that *Cobian* does not teach or suggest the recited coupling of the first band electrode with the first conductor. The Office Action attempts to modify the lead design of *Cobian* using the electrode coupling design shown in *Iwaszkiewicz*.

As previously discussed, *Iwaszkiewicz* forms a connection between a single coiled conductor and an electrode by initially inserting a wire through an insulative layer. Then, the coiled conductor is pushed through the inside of the insulative layer. According to the design of *Iwaszkiewicz*, the force of coiled conductor against the wire bends the wire as the coiled conductor is inserted through the insulative layer. See col. 5, lines 28-36 and Figs. 3 and 4 of *Iwaszkiewicz*. The bent wire lies against the conductor and extends through the insulative layer. The wire is then bent on the outside of the insulative layer to accommodate a band electrode.

Modifying *Cobian* to include a wire coupling between an interior conductor and a band electrode proceeds against the explicit teachings of *Cobian*. Specifically, *Cobian* teaches that it is important to avoid defects in or damage to the insulative sheathings of the wire conductors (e.g., cuts and the like). For example, *Cobian* provides a physical barrier to prevent a stylet from damaging the insulative sheathings when the stylet is inserted within the lumen of the medical lead of *Cobian*. Col. 8, lines 44-47 of *Cobian*. However, the suggested wire coupling design of *Iwaszkiewicz* would operate in a manner similar to the insertion of a stylet without the protective barrier. According to the modification proffered by the Office Action, the wire would come into direct contact with the

insulative sheathings of the conductors thereby exposing the insulative sheathings to potential damage by the inserted wire. Because Cobian explicitly teaches against the proffered modification, the rejection is improper. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).

Moreover, the proposed addition of the two bridging wires of *Iwaszkiewicz* to the lead of *Cobian* does not appear to be practical, and would likely lead to additional problems in manufacturing such a lead. If uninsulated conductors are used (as taught in *Iwaszkiewicz*), neither reference teaches how the conductors are coaxially intertwined and longitudinally compressed in order to provide the mechanical force required to bend the bridging wires into position, without creating electrical contact between the two conductors. Without such teaching, the methods of *Iwaszkiewicz* effectively render the two conductors a single conductor. Also, if insulated conductors are used (as taught by *Cobian*), neither reference teaches how (or when) the insulated conductors would be stripped at the exact location of the inner portion of the bridging wire of *Iwaszkiewicz*.<sup>1</sup>

Furthermore, a section of stripped conductor will be thinner than an adjacent section of insulated conductor, and the outer diameter of the stripped conductor when coiled will necessarily be smaller than the outer diameter of the adjacent coils of insulated conductor. Thus, the bent wire of *Iwaszkiewicz* would rest against the insulative sheathings of the adjacent conductors due their greater diameter and would not contact (physically or electrically) the proposed stripped conductor.

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<sup>1</sup> During the examiner interview, the Examiner raised the argument that it would be inherent to strip the conductors of *Cobian* and combine with *Iwaszkiewicz*.. Appellant respectfully disagrees. *Iwaszkiewicz* slides the single, bare coiled conductor as a separate element through the outer insulator after the bridging wires are inserted through the insulator. In distinct contrast, *Cobian*'s conductor is insulated. Thus, an additional step of stripping the *Cobian* insulated conductor would be necessary (in addition to cutting an opening in the outer insulator).

Other portions of *Iwaszkiewicz* also teach away from the claimed subject matter. The solution taught in *Iwaszkiewicz* for adding a second conductor is to place another coiled conductor inside the first conductor, with a smaller diameter, and separate the two conductors with another insulative sleeve. *Iwaszkiewicz*, col. 4, lines 29-32. Furthermore, *Iwaszkiewicz* teaches that this second conductor is not electrically connected to its electrode with bridging wires, but rather by conventional techniques of the prior art. *Iwaszkiewicz*, col. 6, lines 9-14.

For these reasons, the rejection of record fails to establish a suggestion, teaching or motivation to combine the *Cobian* and *Iwaszkiewicz* references, and even if combinable, such combination failed to disclose, teach, or suggest all the elements recited in independent Claim 43. Appellant respectfully submits that the Examiner has not established a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to make the invention as recited in Claim 43. Therefore, independent Claim 43 and its dependent claims are patentable over the cited prior art.

Accordingly, the Appellant respectfully requests that the § 103(a) rejection of Claims 43, 44, 52 and 53 be withdrawn and that Claims 43, 44, 52 and 53 be passed to allowance.

**F. CLAIM 62**

Independent Claim 62 recites a medical lead that includes:

a body member having a length, a surface, a proximal end portion and a distal end portion;

- a first conductor extending substantially the length of the body member;
- a first tunnel extending from the surface to the first conductor in the distal end portion;
- a second tunnel extending from the surface to the first conductor in the distal end portion;
- a first conductive link within the first tunnel and electrically connected to the first conductor;
- a second conductive link within the second tunnel and electrically connected to the first conductor;
- a first electrode positioned at the distal end portion of the body member, and wherein the first conductive link and the second conductive link are electrically connected to the first electrode;
- a second conductor extending substantially the length of the body member, and wherein the first conductor and the second conductor are each spaced about the same distance from a longitudinal axis of the body member;
- a third tunnel extending from the surface to the second conductor in the distal end portion;
- a fourth tunnel extending from the surface to the second conductor in the distal end portion;
- a third conductive link within the third tunnel and electrically connected to the second conductor;
- a fourth conductive link within the fourth tunnel and electrically connected to the second conductor; and
- a second electrode positioned at the distal end portion of the body member, and wherein the third conductive link and the fourth conductive link are electrically connected to second electrode.

The Appellant incorporates by reference the arguments made with regard to independent Claim 43, as grounds for the failure of the Examiner to establish that the *Cobian* and *Iwaszkiewicz* references, either alone or in combination, disclose, teach, or suggest all the elements recited in independent Claim 62.

Additionally, both *Cobian* and *Iwaszkiewicz* describe electrically connecting a second electrode of a medical lead to a second conductor within the lead. *Cobian* teaches electrically connecting the conductor and electrode by welding or soldering. See *Cobian*, col. 7, lines 44-50,

*incorporating U.S. Patents No. 4,922,607 and 5,007,435 by reference. Iwaszkiewicz teaches connecting the conductor and electrode by prior art techniques other than the technique of using bridging wires to connect the first conductor and electrode. Iwaszkiewicz, col. 6, lines 9-14. Neither reference, however, teaches third and fourth conductive links within third and fourth tunnels in a body member of the lead to electrically connect the second conductor to the second electrode, as recited in independent Claim 62.*

For these reasons, the Examiner fails to establish that the *Cobian* and *Iwaszkiewicz* references, either alone or in combination, disclose, teach, or suggest all the elements of independent Claim 62. Nor does the Examiner establish a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to make the invention as recited in independent Claim 62. Therefore, independent Claim 62 is patentable over the cited prior art.

Accordingly, the Appellant respectfully requests that the § 103(a) rejection of independent Claim 62 be withdrawn and that independent Claim 62 be passed to allowance.

**G. CLAIM 63**

Independent Claim 63 recites a medical lead including:

a body member having a wall, a proximal end portion and a distal end portion;  
a first conductor and a second conductor within the wall and extending substantially from the proximal end portion to the distal end portion, and wherein the first conductor and the second conductor are each spaced about the same distance from a longitudinal axis of the body member;

a first band electrode and a second band electrode positioned at a one of the proximal end portion and the distal end portion;

a first conductive link extending through the wall at the one of the proximal end portion and the distal end portion and electrically connecting the first conductor and the first electrode;

a second conductive link extending through the wall at the one of the proximal end portion and the distal end portion and electrically connecting the first conductor and the first electrode; and

a third conductive link extending through the wall at the one of the proximal end portion and the distal end portion and electrically connecting the second conductor and the second electrode.

The Appellant incorporates by reference the arguments made with regard to Claim 43, as grounds for the failure of the Examiner to establish that the *Cobian* and *Iwaszkiewicz* references, either alone or in combination, disclose, teach, or suggest all the elements of independent Claim 63.

Additionally, both the *Cobian* and *Iwaszkiewicz* references describe medical leads with two connectors at a proximal end and two electrodes at a distal end, electrically connected by two conductors. In the *Cobian* reference, a proximal connector pin is electrically connected to a distal tip electrode, and a proximal ring connector element is electrically connected to a ring electrode at the distal end of the lead. *Cobian*, col. 7, lines 42-49. *Iwaszkiewicz* describes a coaxial connector for use at the proximal end of the lead, having a tip electrode and ring electrode connected to a tip electrode and ring electrode, respectively, at the distal end of the lead. *Iwaszkiewicz*, col. 6, lines 19-30. In both references, a first ring connector at the proximal end and a second ring electrode at the distal end are electrically connected by a first conductor. Neither reference describes a lead with a second band electrode at either the proximal or distal end of the lead electrically connected to a

second conductor. Instead, the references consistently describe the second conductor as electrically connected to a pin connector and a tip electrode.

For these reasons, the Examiner fails to establish that the *Cobian* and *Iwaszkiewicz* references, either alone or in combination, disclose, teach, or suggest all the elements of independent Claim 63. Nor does the Examiner establish a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to make the invention as recited in independent Claim 63. Therefore, independent Claim 63 is patentable over the cited prior art.

Accordingly, the Appellant respectfully requests that the § 103(a) rejection of independent Claim 63 be withdrawn and that independent Claim 63 be passed to allowance.

#### **H. CLAIMS 67 and 69**

Independent Claim 67 recites a medical lead that includes:

a lead body having an insulator and having a first conductor and a second conductor spaced substantially equidistant from the axis of the lead body, and wherein the insulator comprises,

a first region formed by removal of at least a portion of the insulator in a distal end portion of the lead body, the first region exposing at least a portion of the first conductor,

a second region formed by removal of at least a portion of the insulator in the distal end portion of the lead body, the second region exposing at least a portion of the first conductor,

a third region formed by removal of at least a portion of the insulator in the distal end portion of the lead body, the third region exposing at least a portion of the second conductor,

a fourth region formed by removal of at least a portion of the insulator in the distal end portion of the lead body, the fourth region exposing at least a portion of the second conductor;

a first electrode electrically connected to the first conductor through the first region and electrically connected to the first conductor through the second region; and

a second electrode electrically connected to the second conductor through the third region and electrically connected to the second conductor through the fourth region.

The Appellant incorporates by reference the arguments made with regard to independent Claim 43, as grounds for the failure of the Examiner to establish that the *Cobian* and *Iwaszkiewicz* references, either alone or in combination, disclose, teach, or suggest all the elements of independent Claim 67.

Additionally, the Examiner fails to establish that *Cobian* and *Iwaszkiewicz* disclose, teach, or suggest first/second and third/fourth regions formed by the removal of respective portions of an insulator in a lead body to expose at least a portion of first and second conductors, respectively.

By reference, *Cobian* describes a first conductor being pulled out through a hole in a sleeve and laser welded to a ring electrode. *U.S. Patent No. 4,922,607, col. 5, lines 7-18, incorporated by reference at Cobian, col. 7, lines 44-50.* Thus, only a single hole in the sleeve is taught to expose a portion of the conductor.

*Iwaszkiewicz* describes bridging wires placed in holes pierced in an insulating tube before a conductor is introduced into the interior of the tube. *Col. 5, lines 16-26; Fig. 3.* As a result, there is no conductor to be exposed when the holes are pierced in the insulating tube, and when the conductor is introduced into the tube, the holes have been filled with bridging wires. As such, in

neither reference are first and second regions formed by removal of portions of an insulator to expose a portion of a conductor.

For these reasons, the Examiner fails to establish that the *Cobian* and *Iwaszkiewicz* references, either alone or in combination, disclose, teach, or suggest all the elements of independent Claim 67. Nor does the Examiner establish a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to make the invention as recited in independent Claim 67. Therefore, independent Claim 67 and its dependent claims are patentable over the cited prior art.

Accordingly, the Appellant respectfully requests that the § 103(a) rejection of Claims 67 and 69 be withdrawn and that Claims 67 and 69 be passed to allowance.

**I. CLAIMS 71, 72 and 73**

Independent Claim 71 recites a medical lead including:

a lead body having an insulator and a first conductor and a second conductor, the first conductor and the second conductor spaced about the same distance from a longitudinal axis of the lead body, and wherein the insulator comprises,

a first tunnel region formed by removal of at least a first portion of the insulator from the lead body, at least a portion of the first tunnel region formed to expose at least a first portion of the first conductor,

a second tunnel region formed by removal of at least a second portion of the insulator from the lead body, at least a portion of the second tunnel region formed to expose at least a second portion of the first conductor,

a third tunnel region formed by removal of at least a third portion of the insulator from the lead body, at least a portion of the third tunnel region formed to expose at least a first portion of the second conductor,

a fourth tunnel region formed by removal of at least a fourth portion of the insulator from the lead body, at least a portion of the fourth tunnel region formed to

expose at least a second portion of the second conductor, wherein the first, second, third and fourth tunnel regions are positioned on a distal end portion of the lead body;  
a first conductive link having at least a portion thereof positioned within the first tunnel region, the first conductive link electrically connected to first conductor;  
a second conductive link positioned within the second tunnel region, the second conductive link electrically connected to the first conductor;  
a third conductive link having at least a portion thereof positioned within the third tunnel region, the third conductive link electrically connected to second conductor;  
a fourth conductive link positioned within the second tunnel region, the fourth conductive link electrically connected to the second conductor;  
a first band electrically connected to the first conductive link and electrically connected to the second conductive link; and  
a second band electrically connected to the third conductive link and electrically connected to the fourth conductive link.

The Appellant incorporates by reference the arguments made with regard to independent Claim 43, as grounds for the failure of the Examiner to establish that the *Cobian* and *Iwaszkiewicz* references, either alone or in combination, disclose, teach, or suggest all the elements of independent Claim 71.

Additionally, the Examiner fails to establish that *Cobian* and *Iwaszkiewicz* disclose, teach, or suggest first/second and third/fourth tunnel regions formed at the distal end portion of the lead body by the removal of first/second and third/fourth portions, respectively, of an insulator in a lead body, where at least a portion of the tunnel regions are formed to expose at least a portion of first and second conductors, respectively.

By reference, *Cobian* describes a first conductor being pulled out through a hole in a sleeve and laser welded to a ring electrode. *U.S. Patent No. 4,922,607, col. 5, lines 7-18, incorporated by reference at Cobian, col. 7, lines 44-50.* Thus, only a single hole in the sleeve is taught to expose a portion of the conductor.

*Iwaszkiewicz* describes bridging wires placed in holes pierced in an insulating tube before a conductor is introduced into the interior of the tube. *Col. 5, lines 16-26; Fig. 3*. As a result, there is no conductor to be exposed when the holes are pierced in the insulating tube, and when the conductor is introduced into the tube, the holes have been filled with bridging wires. As such, in neither reference are first and second regions formed by removal of portions of an insulator to expose a portion of a conductor.

For these reasons, the Examiner fails to establish that the *Cobian* and *Iwaszkiewicz* references, either alone or in combination, disclose, teach, or suggest all the elements of independent Claim 71. Nor does the Examiner establish a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to make the invention as recited in independent Claim 71. Therefore, independent Claim 71 and its dependent claims are patentable over the cited prior art.

Accordingly, the Appellant respectfully requests that the § 103(a) rejection of Claims 71-73 be withdrawn and that Claims 71-73 be passed to allowance.

**J. CLAIMS 75-78**

Independent Claim 75 recites a medical lead that includes:

a lead body having an insulator, a first conductor and a second conductor each spaced about the same distance from a longitudinal axis of the body member, wherein the insulator comprises,

a first opening formed by removal of at least a first portion of the insulator from a distal end portion of the lead body, at least a portion of the first opening formed to expose at least a first portion of the first conductor,

a second opening formed by removal of at least a second portion of the insulator from a distal end portion of the lead body, at least a portion of the second opening formed to expose at least a second portion of the first conductor,

a third opening formed by removal of at least a third portion of the insulator from a distal end portion of the lead body, at least a portion of the third opening formed to expose at least a first portion of the second conductor, and

a fourth opening formed by removal of at least a fourth portion of the insulator from a distal end portion of the lead body, at least a portion of the fourth opening formed to expose at least a second portion of the second conductor;

a first conductive link within the first opening, the first conductive link electrically connected to the first conductor;

a second conductive link within the second opening, the second conductive link electrically connected to the first conductor;

a third conductive link within the third opening, the third conductive link electrically connected to the second conductor;

a fourth conductive link within the fourth opening, the fourth conductive link electrically connected to the second conductor;

a first band electrode electrically connected to the first conductive link to electrically connect the first band to the first conductor, and electrically connected to the second conductive link to electrically connect the first band to the first conductor; and

a second band electrode electrically connected to the third conductive link to electrically connect the second band to the second conductor, and electrically connected to the fourth conductive link to electrically connect the second band to the second conductor.

The Appellant incorporates by reference the arguments made with regard to independent Claim 43, as grounds for the failure of the Examiner to establish that the *Cobian* and *Iwaszkiewicz* references, either alone or in combination, disclose, teach, or suggest all the elements of independent Claim 75.

Additionally, the Examiner fails to establish that *Cobian* and *Iwaszkiewicz* disclose, teach, or suggest first/second and third/fourth openings formed at the distal end portion of the lead body by the removal of first/second and third/fourth portions, respectively, of an insulator in a lead body, where

at least a portion of the tunnel regions are formed to expose at least a portion of first and second conductors, respectively.

By reference, *Cobian* describes a first conductor being pulled out through a hole in a sleeve and laser welded to a ring electrode. *U.S. Patent No. 4,922,607, col. 5, lines 7-18, incorporated by reference at Cobian, col. 7, lines 44-50.* Thus, only a single hole in the sleeve is taught to expose a portion of the conductor.

*Iwaszkiewicz* describes bridging wires placed in holes pierced in an insulating tube before a conductor is introduced into the interior of the tube. *Col. 5, lines 16-26; Fig. 3.* As a result, there is no conductor to be exposed when the holes are pierced in the insulating tube, and when the conductor is introduced into the tube, the holes have been filled with bridging wires. As such, in neither reference are first and second regions formed by removal of portions of an insulator to expose a portion of a conductor.

For these reasons, the Examiner fails to establish that the *Cobian* and *Iwaszkiewicz* references, either alone or in combination, disclose, teach, or suggest all the elements of independent Claim 75. Nor does the Examiner establish a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to make the invention as recited in independent Claim 75. Thus, independent Claim 75 and its dependent claims are patentable over the cited prior art.

Accordingly, the Appellant respectfully requests that the § 103(a) rejection of Claims 75-78 be withdrawn and that Claims 75-78 be passed to allowance.

**II. GROUND OF REJECTION #2**

The rejection of Claims 43, 44, 52, 53, 62, 63, 67-69, 71-73 and 75-78 under 35 U.S.C. § 103(a) is improper and should be withdrawn.

**A. OVERVIEW**

Claims 43, 44, 52, 53, 62, 63, 67-69, 71-73 and 75-78 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iwaszkiewicz*.

**B. CLAIMS 43, 44, 52, 53, 62, 63, 67, 69, 71-73 and 75-78**

The Office Action mailed February 23, 2005, argues first that *Iwaszkiewicz* discloses the claimed invention except for the duplication of conductor, openings, conductive links and electrodes to provide a second band electrode at the distal end of a medical lead. *See, Office Action, pages 4-5*. The Office Action also argues that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the lead as taught by *Iwaszkiewicz* to provide a second electrode by using first, second, third and fourth conductors. *See, Office Action, page 5*. The Appellant will address these rejections separately.

i. **DUPLICATION OF PARTS**

Appellant respectfully submits that “duplication of parts” of *Iwaszkiewicz* is not obvious with respect to Appellant’s invention. Since each of the independent Claims 43, 62, 63, 67, 71 and 75 recite first and second conductors that are each spaced about the same distance from a longitudinal axis of the body member (or spaced substantially equidistant from the axis of the lead body), mere “duplication” of *Iwaszkiewicz*’ single conductor would not result in Appellant’s invention, as claimed. The disclosure of *Iwaszkiewicz* fails to allow “duplication” of the single conductor shown in *Iwaszkiewicz* as the conductor is illustrated as coiled, virtually unitary (no space between the coils), and extends substantially the length of the lead. Accordingly, there cannot be two such conductors that are “spaced about the same distance from a longitudinal axis of the body member” (or substantially equidistant from the axis). As such, Appellant respectfully submits that “duplication” of *Iwaszkiewicz*’ single conductor cannot produce the Appellant’s claimed invention (as stated previously, duplication of *Iwaszkiewicz* is substantially problematic).

ii. **OBVIOUSNESS**

The Appellant notes that the Examiner’s argument that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the lead as taught by *Iwaszkiewicz* to provide a second electrode by using first, second, third and fourth conductors applies only to dependent Claims 69 and 78. Independent Claims 43, 62, 63, 67, 71 and 75 do not recite third and fourth conductors.

Furthermore, the Examiner's rejection is merely conclusory, and fails to establish a prima facie case of obviousness. The rejection simply argues that it "is known in the art" to have multiple conductors at about the same distance from the longitudinal axis of the body member. This rejection, in essence, appears to be the same as the Examiner's § 103(a) rejection over *Cobian* and *Iwaszkiewicz*. Thus, Appellant incorporates by reference the arguments made with regard to independent Claim 43, as grounds for the failure of the Examiner to establish this obviousness in view of the *Iwaszkiewicz* reference with respect to all claims rejected under this ground. The Examiner also provides a grab-bag of motivations for the proposed modification of the *Iwaszkiewicz* lead:

To provide a second duplicate electrode on the distal end of the lead body to provide additional therapy to the body with the same lead and use multiple conductors spiraled around the same distance from a longitudinal axis of the body member to provide a lumen for insertion of additional elements and/or provides additional rigidity/flexibility to assist in insertion and adaptation of the lead and/or to provide a smaller lead and/or to provide a redundant connection to the electrode in case one of the conductors breaks. *Office Action, page 5.*

The Appellant notes that the motivations are both contradictory (provides both additional rigidity and flexibility) and addressed to limitations not recited in the claims at issue (providing redundant connections to the electrode in case a conductor breaks).

### C. CONCLUSION

For these reasons, the Examiner fails to establish that the *Iwaszkiewicz* reference discloses, teaches, or suggests all the elements of independent Claims 43, 62, 63, 67, 71 and 75. Nor does the

Examiner establish a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to make the invention as recited in independent Claims 43, 62, 63, 67, 71 and 75. Thus, independent Claims 43, 62, 63, 67, 71 and 75 and their dependent claims are patentable over the cited prior art.

Accordingly, the Appellant respectfully requests that the § 103(a) rejection of Claims 43, 44, 52, 53, 62, 63, 67, 69, 71-73 and 75-78 under § 103(a) as being unpatentable over *Iwaszkiewicz* be withdrawn and that Claims 43, 44, 52, 53, 62, 63, 67, 69, 71-73 and 75-78 be passed to allowance.

**III. GROUND OF REJECTION #3**

The rejection of Claims 54, 66 and 70 under 35 U.S.C. 102(b) and, in the alternative, under 35 U.S.C. 103(a), is improper and should be withdrawn.

**A. OVERVIEW**

Claims 54, 66 and 70 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over *Iwaszkiewicz*.

**B. STANDARD**

A prior art reference anticipates a claimed invention under 35 U.S.C. § 102 only if every element of the claimed invention is identically shown in that single reference, arranged as they are in the claims. (*MPEP* § 2131; *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990)). Anticipation is only shown where each and every limitation of the claimed invention is found in a single prior art reference. (*MPEP* § 2131; *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985)).

**C. ANTICIPATION OF DEPENDENT CLAIMS**

Claim 54 depends from independent Claim 43. Claim 66 depends from independent Claim 63. Claim 70 depends from independent Claim 67. Independent Claims 43, 63 and 67 stand rejected

under 35 U.S.C. § 103(a) as unpatentable over *Cobian* in view of *Iwaszkiewicz* and as unpatentable under 35 U.S.C. § 103(a) over *Iwaszkiewicz* alone.

The Examiner does not explain how these dependent claims are anticipated by a reference, when the Examiner has failed to establish prima facie that the base claims are anticipated by such reference. If each and every element of an independent claim is not found in a single prior art reference, then each and every element of its dependent claim cannot be found in a single reference. Assuming that the Examiner's meaning is that each and every additional limitation of the dependent claims are found in the *Iwaszkiewicz* reference, the Appellant respectfully disagrees.

**D. CLAIM 54**

Claim 54 depends from independent Claim 43. As shown above, independent Claim 43 is patentable and Appellant incorporates by reference the arguments made with regard to independent Claim 43.<sup>2</sup> As a result, Claim 54 is patentable because of its dependence from an allowable base claim.

In addition, Claim 54 recites an electrode comprising "a first segment and a second segment disposed along a longitudinal dimension of the body member in overlapped relation." The Examiner asserts that this limitation is shown in "the proximal and distal segments of the electrode" of *Iwaszkiewicz*. *Office Action*, page 6. The Appellant respectfully submits that the word "segment" does not appear in the *Iwaszkiewicz* reference. Tip electrodes and ring electrodes (also referred to as

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<sup>2</sup> The Examiner has failed to show or establish that each and every element of independent Claim 43 is found

tubular) are described, but neither is identified as segmented, much less as being disposed in an overlapped relation, as recited in Claim 54. As argued above, if each and every element of independent Claim 43 is not found in the *Iwaszkiewicz* reference, then each and every element of its dependent claim cannot be found in the reference. Nor does the *Iwaszkiewicz* reference teach each and every additional limitation of Claim 54. Therefore, the Examiner has failed to establish that Claim 54 is anticipated by the *Iwaszkiewicz* reference

Furthermore, the Examiner makes no argument that “a first segment and a second segment disposed along a longitudinal dimension of the body member in overlapped relation,” as recited in Claim 54, is obvious in view of the *Iwaszkiewicz* reference.

For these reasons, the Examiner fails to establish that the *Iwaszkiewicz* reference either anticipates or renders obvious Claim 54. Thus, Claim 54 is patentable over the cited prior art. Accordingly, the Appellant respectfully requests that the § 102 and § 103(a) rejections of Claim 54 be withdrawn and that Claim 54 be passed to allowance.

**E. CLAIMS 66 AND 70**

Claims 66 and 70 recite spirally wound conductors, “with each turn being at an angle between about 10 degrees to about 80 degrees.” As shown above, independent Claims 63 and 67 (from which Claims 66 and 70 depend, respectfully) is patentable and Appellant incorporates by

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in *Iwaszkiewicz*. Thus, any rejection based upon 102 is without merit.

reference the arguments made with regard to independent Claims 63 and 67.<sup>3</sup> As a result, Claims 66 and 70 are patentable because of their dependence from an allowable base claim.

As argued above, if each and every element of independent Claims 63 and 67 are not found in a single prior art reference, then each and every element of their dependent claims cannot be found in a single reference, and the Examiner has failed to establish that Claims 66 and 70 are anticipated by the *Iwaszkiewicz* reference.

Claims 66 and 70 depends from independent Claims 63 and 67, respectively. As shown above, Claims 63 and 67 are patentable. As a result, Claims 66 and 70 are patentable because of their dependence from allowable base claims.

Furthermore, the Examiner asserts, without citation, that “it was known that medical leads use conductors spiraled from about 10 degrees to about 80 degrees to provide greater or lesser torque and flexibility to the leads.” Such an assertion is tantamount to taking Official Notice, which is only appropriate when the facts beyond the record are capable of such instant and unquestionable demonstration as to defy dispute. The Appellant respectfully submits that the Examiner’s general assertion of obviousness is merely conclusory, and fails to establish a *prima facie* case of obviousness.

For these reasons, the Examiner fails to establish that the *Iwaszkiewicz* reference either anticipates or renders obvious Claims 66 and 70. Therefore, Claims 66 and 70 are patentable over

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<sup>3</sup> The Examiner has failed to show or establish that each and every element of independent Claims 63 and 67 is found in *Iwaszkiewicz*. Thus, any rejection based upon 102 is without merit

the cited prior art. Accordingly, the Appellant respectfully requests that the § 102 and § 103(a) rejections of Claims 66 and 70 be withdrawn and that Claims 66 and 70 be passed to allowance.

**IV. GROUND OF REJECTION #4**

The rejection of Claims 45-50 and 56 under 35 U.S.C. § 103(a) is improper and should be withdrawn.

**A. OVERVIEW**

Claims 45-50 and 56 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iwaszkiewicz*.

**B. CLAIMS 45 AND 56**

Claims 45 and 56 depend from independent Claim 43. As shown above, independent Claim 43 is patentable and Appellant incorporates by reference the arguments made with regard to independent Claim 43. As a result, Claims 45 and 56 are patentable because of their dependence from an allowable base claim.

In addition, Claims 45 and 56 recite that the first conductor is “embedded” in the wall of the body member of the lead. The Appellant respectfully submits that the conductor of *Iwaszkiewicz* cannot be considered “embedded” in the outer insulator. The outer insulator is appropriately

described in *Iwaszkiewicz* as “surrounding” the conductor, because the outer insulator is rubber tubing into which the conductor is slid. The Appellant respectfully submits that this does not teach “embedding” the conductors in the sense of “burying” or “submerging” them in the body member wall so that they are surrounded on all sides by the wall, as described in the Appellant’s Specification. *Application: page 7, lines 4-7 and lines 14-16; page 12, lines 20-23; Figures 2, 4, 5 and 8.*

For these reasons, the Examiner fails to establish that the *Iwaszkiewicz* reference discloses, teaches, or suggests all the elements of Claims 45 and 56. Thus, Claims 45 and 56 are patentable over the cited prior art. Accordingly, the Appellant respectfully requests that the § 103(a) rejection of Claims 45 and 56 be withdrawn and that Claims 45 and 56 be passed to allowance.

**C. CLAIMS 46-50**

Claims 46-50 depend, directly or indirectly, from independent Claim 43. As shown above, Claim 43 is patentable and Appellant incorporates by reference the arguments made with regard to independent Claim 43. As a result, Claims 46-50 are patentable because of their dependence from an allowable base claim.

Accordingly, the Appellant respectfully requests that the § 103(a) rejection of Claims 46-50 be withdrawn and that Claims 46-50 be passed to allowance.

**V. GROUND OF REJECTION # 5**

The rejection of Claims 51, 64, 74 and 77 under 35 U.S.C. § 103(a) is improper and should be withdrawn.

**A. OVERVIEW**

Claims 51, 64, 74 and 77 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iwaszkiewicz* in view of U.S. Patent No. 5,433,742 to Willis (“*Willis*”) or U.S. Patent No. 5,016,646 to Gotthardt, *et al.* (“*Gotthardt*”).

**B. CLAIMS 51, 64, 74 AND 77**

Claims 51, 64, 74 and 77 depend, directly or indirectly, from independent Claims 43, 63, 71 and 75, respectively. As shown above, independent Claims 43, 63, 71 and 75 are patentable and Appellant incorporates by reference the arguments made with regard to independent Claims 43, 63, 71 and 75. As a result, Claims 51, 64, 74 and 77 are patentable because of their dependence from allowable base claims.

Furthermore, the Appellant respectfully submits that a person of ordinary skill in the art at the time of the invention would not have been motivated to use conductive epoxy in place of the bridging wires of the *Iwaszkiewicz* reference, because there would have been no reasonable expectation of success. *Iwaszkiewicz* teaches inserting bridging wires radially through the walls of a tubular outer insulator, sliding a coiled conductor into the interior of the insulator to fold over the

inner end of the bridging wire and make electrical contact, and sliding a ring electrode over the outside of the insulator to fold over the outer end of the bridging wire and make electrical contact.

Substituting conductive epoxy for the bridging wires would not succeed whether the conductor and electrode were installed while the epoxy was soft or while it was hard. Assuming the conductive epoxy were inserted into the holes pierced for the bridging wires, while the epoxy was still soft, the leading edge of both the conductor coil and the electrode would wipe away at least the portion of epoxy that extended beyond the inner and outer surface, respectively, of the insulator. Some portion of the epoxy lying just below the surface could also be carried away, as well. As a result, an electrical connection between the conductor or the electrode could not be assured.

If the coiled conductor and electrode were installed after the conductive epoxy had hardened, two problems might arise. If some portion of the epoxy extended beyond the inner or outer surface it would act as a physical barrier, preventing the conductor or electrode, respectively, from being slid fully into position. If the epoxy had shrunk below the surface of the insulator in the drying process, an electrical connection between the conductor or the electrode, once installed, could not be assured. Thus, the person of ordinary skill in the art would have no reasonable expectation of success in modifying the *Iwaszkiewicz* reference by the teachings of *Willis* or *Gotthardt*.

For these reasons, the Examiner fails to establish that the *Iwaszkiewicz*, *Willis* and *Gotthardt* references, either alone or in combination, disclose, teach, or suggest all the elements of Claims 51, 64, 74 and 77. Thus, Claims 51, 64, 74 and 77 are patentable over the cited prior art. Accordingly,

the Appellant respectfully requests that the § 103(a) rejection of Claims 51, 64, 74 and 77 be withdrawn and that Claims 51, 64, 74 and 77 be passed to allowance.

**VI. GROUND OF REJECTION #6**

The rejection of Claim 55 under 35 U.S.C. § 103(a) is improper and should be withdrawn.

**A. OVERVIEW**

Claim 55 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Iwaszkiewicz*.

**B. CLAIM 55**

Claim 55 depends from independent Claim 43. As shown above, Claim 43 is patentable and Appellant incorporates by reference the arguments made with regard to independent Claim 43. As a result, Claim 55 is patentable because of its dependence from an allowable base claim.

Furthermore, the Examiner merely asserts that *Iwaszkiewicz* discloses a thin film electrode.

Claim 55 also recites the limitation that the thin film electrode comprises:

a first layer of a metal selected from a group consisting of titanium, chromium, nickel and aluminum and having a thickness less than about 5 microns and a second layer of a metal selected from the group consisting of gold, platinum, platinum-iridium, silver and copper and having a thickness between about 500 angstroms and about 50 microns.

The Examiner ignores the limitations of claim 55 stating that the limitations are merely a design choice “because Applicant has not disclosed that the thin film electrode...is used for a particular purpose or solves a stated problem.” Additionally, the Examiner cites no suggestion or motivation, either in the *Iwaszkiewicz* reference or in the knowledge generally available to one of ordinary skill in the art, to modify *Iwaszkiewicz* to include the limitations of Claim 55.

Appellant submits that Appellant is not required to provide a disclosure why structural limitations, such as the limitations of claim 55, should be given patentable weight. In any event, Appellant notes that page 5 of the application explains that the “thin film electrodes...do not detract from the flexibility of the resulting catheter and its ability to be readily steered through the epidural space.” Accordingly, it cannot be said the limitations of claim 55 are merely a matter of “design choice.”

For these reasons, the Examiner fails to establish that the *Iwaszkiewicz* reference discloses, teaches, or suggests all the elements of Claim 55. Thus, Claim 55 is patentable over the cited prior art. Accordingly, the Appellant respectfully requests that the § 103(a) rejection of Claim 55 be withdrawn and that Claim 55 be passed to allowance.

**SUMMARY**

The Appellant has demonstrated that the present invention as claimed is clearly distinguishable over the prior art cited of record. Therefore, the Appellant respectfully requests the Board of Patent Appeals and Interferences to reverse the final rejections of the Examiner and instruct the Examiner to issue a notice of allowance of all claims.

The Appellant has enclosed the appropriate fee to cover the cost of this APPEAL BRIEF. The Appellant does not believe that any additional fees are due. However, the Commissioner is hereby authorized to charge any additional fees or credit any overpayments to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

DAVIS MUNCK, P.C.

Date: 8/23/2005

  
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**APPENDIX A**

**CLAIMS APPENDIX**

1-42. (Canceled).

43. A neurostimulating lead comprising:  
a body member having a wall, a proximal end portion and a distal end portion;  
a first conductor within the wall of the body member and extending between the proximal end portion and the distal end portion;  
a second conductor within the wall of the body member and extending between the proximal end portion and the distal end portion, and wherein the first conductor and the second conductor are each spaced about the same distance from a longitudinal axis of the body member;  
a first opening in the wall in the distal end portion leading to the first conductor;  
a second opening in the wall in the distal end portion leading to the first conductor;  
a third opening in the wall in the distal end portion leading to the second conductor;  
a first conductive link within the first opening to electrically connect to the first conductor;  
a second conductive link within the second opening to electrically connect to the first conductor;  
a third conductive link within the third opening to electrically connect to the second conductor;  
a first band electrode positioned at the distal end portion and proximate the outer surface of the body member and electrically connected to the first conductive link and to the second conductive link; and  
a second band electrode positioned at the distal end portion proximate the outer surface of the body member and electrically connected to the third conductive link.

44. The neurostimulating lead in accordance with Claim 43 further comprising at least one connector having a contact electrically joined to the first conductor at the proximal end portion of the body member and adapted to connect the lead to a neurostimulator.

45. The neurostimulating lead in accordance with Claim 43 wherein the body member is tubular and having an annular wall defining an internal lumen extending between the proximal end portion and the distal end portion, and wherein the first conductor being spiral wound and embedded in the annular wall.

46. The neurostimulating lead in accordance with Claim 45 wherein the body member comprises polyurethane and has an outer diameter of about 2 French and an internal diameter of about 0.012 inch.

47. The neurostimulating lead in accordance with Claim 46 wherein the first conductor has a substantially rectangular cross-section about 0.004 inch wide by about 0.002 inch high.

48. The neurostimulating lead in accordance with Claim 47 wherein the first conductor comprises metal, and wherein the metal is selected from a group consisting of stainless steel, MP35N, titanium, tantalum, tungsten, platinum, and silver.

49. The neurostimulating lead in accordance with Claim 45 wherein the first conductor comprises turns, with each turn being at an angle between about 10 degrees to about 80 degrees from a longitudinal axis of the body member.

50. The neurostimulating lead in accordance with Claim 49 wherein the electrode comprises a thin film electrode.

51. The neurostimulating lead in accordance with Claim 43 wherein the first conductive link and the second conductive link comprise conductive epoxy.

52. The neurostimulating lead in accordance with Claim 43 wherein the first conductive link and the second conductive link comprise an electroplated conductive link.

53. The neurostimulating lead in accordance with Claim 52 wherein the electroplated conductive link comprises a metal selected from a group consisting of gold, silver, platinum, platinum-iridium and titanium.

54. The neurostimulating lead in accordance with Claim 43 wherein the electrode comprises a thin film electrode, and the electrode comprises a first segment and a second segment disposed along a longitudinal dimension of the body member in overlapped relation, the first segment and the second segment adapted to be electrically connected to a one of a voltage of positive polarity, a voltage of negative polarity, and zero voltage.

55. The neurostimulating lead in accordance with Claim 43 wherein the electrode comprises a thin film electrode, the thin film electrode comprising a first layer of a metal selected from a group consisting of titanium, chromium, nickel and aluminum and having a thickness less than about 5 microns and a second layer of a metal selected from the group consisting of gold, platinum, platinum-iridium, silver and copper and having a thickness between about 500 angstroms and about 50 microns.

56. The neurostimulating lead in accordance with Claim 43 wherein the first conductor is embedded within the wall of the body member.

57-61. (Canceled).

62. A medical lead comprising:

- a body member having a length, a surface, a proximal end portion and a distal end portion;
- a first conductor extending substantially the length of the body member;
- a first tunnel extending from the surface to the first conductor in the distal end portion;
- a second tunnel extending from the surface to the first conductor in the distal end portion;
- a first conductive link within the first tunnel and electrically connected to the first conductor;
- a second conductive link within the second tunnel and electrically connected to the first conductor;
- a first electrode positioned at the distal end portion of the body member, and wherein the first conductive link and the second conductive link are electrically connected to the first electrode;
- a second conductor extending substantially the length of the body member, and wherein the first conductor and the second conductor are each spaced about the same distance from a longitudinal axis of the body member;
- a third tunnel extending from the surface to the second conductor in the distal end portion;
- a fourth tunnel extending from the surface to the second conductor in the distal end portion;
- a third conductive link within the third tunnel and electrically connected to the second conductor;
- a fourth conductive link within the fourth tunnel and electrically connected to the second conductor; and
- a second electrode positioned at the distal end portion of the body member, and wherein the third conductive link and the fourth conductive link are electrically connected to second electrode.

63. A medical lead comprising:

- a body member having a wall, a proximal end portion and a distal end portion;
- a first conductor and a second conductor within the wall and extending substantially from the proximal end portion to the distal end portion, and wherein the first conductor and the second conductor are each spaced about the same distance from a longitudinal axis of the body member;
- a first band electrode and a second band electrode positioned at a one of the proximal end portion and the distal end portion;
- a first conductive link extending through the wall at the one of the proximal end portion and the distal end portion and electrically connecting the first conductor and the first electrode;
- a second conductive link extending through the wall at the one of the proximal end portion and the distal end portion and electrically connecting the first conductor and the first electrode; and
- a third conductive link extending through the wall at the one of the proximal end portion and the distal end portion and electrically connecting the second conductor and the second electrode.

64. The medical lead in accordance with Claim 63 wherein the first conductive link comprises a conductive epoxy.

65. (Canceled)

66. The medial lead in accordance with Claim 63 wherein the first conductor is spirally wound, with each turn being at an angle between about 10 degrees to about 80 degrees from a longitudinal axis of the body member.

67. A medical lead, comprising:  
a lead body having an insulator and having a first conductor and a second conductor spaced substantially equidistant from the axis of the lead body, and wherein the insulator comprises,  
a first region formed by removal of at least a portion of the insulator in a distal end portion of the lead body, the first region exposing at least a portion of the first conductor,  
a second region formed by removal of at least a portion of the insulator in the distal end portion of the lead body, the second region exposing at least a portion of the first conductor,  
a third region formed by removal of at least a portion of the insulator in the distal end portion of the lead body, the third region exposing at least a portion of the second conductor,  
a fourth region formed by removal of at least a portion of the insulator in the distal end portion of the lead body, the fourth region exposing at least a portion of the second conductor;  
a first electrode electrically connected to the first conductor through the first region and electrically connected to the first conductor through the second region; and  
a second electrode electrically connected to the second conductor through the third region and electrically connected to the second conductor through the fourth region.

68. The medical lead in accordance with Claim 67 wherein the lead body further comprises a distal end and a proximal end, and the first region, the second region, the third region, the fourth region, the first electrode and the second electrode are located proximate the distal end of the lead body.

69. (Canceled)

70. The medical lead in accordance with Claim 67 wherein the first conductor and the second conductor are spirally wound, with each turn being at an angle between about 10 degrees to about 80 degrees from a longitudinal axis of the lead.

71. A medical lead, comprising:  
a lead body having an insulator and a first conductor and a second conductor, the first conductor and the second conductor spaced about the same distance from a longitudinal axis of the lead body, and wherein the insulator comprises,  
a first tunnel region formed by removal of at least a first portion of the insulator from the lead body, at least a portion of the first tunnel region formed to expose at least a first portion of the first conductor,  
a second tunnel region formed by removal of at least a second portion of the insulator from the lead body, at least a portion of the second tunnel region formed to expose at least a second portion of the first conductor,  
a third tunnel region formed by removal of at least a third portion of the insulator from the lead body, at least a portion of the third tunnel region formed to expose at least a first portion of the second conductor,  
a fourth tunnel region formed by removal of at least a fourth portion of the insulator from the lead body, at least a portion of the fourth tunnel region formed to expose at least a second portion of the second conductor, wherein the first, second, third and fourth tunnel regions are positioned on a distal end portion of the lead body;  
a first conductive link having at least a portion thereof positioned within the first tunnel region, the first conductive link electrically connected to first conductor;  
a second conductive link positioned within the second tunnel region, the second conductive link electrically connected to the first conductor;  
a third conductive link having at least a portion thereof positioned within the third tunnel region, the third conductive link electrically connected to second conductor;  
a fourth conductive link positioned within the second tunnel region, the fourth conductive link electrically connected to the second conductor;  
a first band electrically connected to the first conductive link and electrically connected to the second conductive link; and  
a second band electrically connected to the third conductive link and electrically connected to the fourth conductive link.

72. The medical lead in accordance with Claim 71 wherein each of the tunnel regions comprise a channel cut in the insulator.

73. The medical lead in accordance with Claim 71 wherein the first conductive link comprises electroplating material.

74. The medical lead in accordance with Claim 71 wherein the first conductive link comprises a conductive epoxy.

75. A medical lead, comprising:  
a lead body having an insulator, a first conductor and a second conductor each spaced about the same distance from a longitudinal axis of the body member, wherein the insulator comprises,  
a first opening formed by removal of at least a first portion of the insulator from a distal end portion of the lead body, at least a portion of the first opening formed to expose at least a first portion of the first conductor,  
a second opening formed by removal of at least a second portion of the insulator from a distal end portion of the lead body, at least a portion of the second opening formed to expose at least a second portion of the first conductor,  
a third opening formed by removal of at least a third portion of the insulator from a distal end portion of the lead body, at least a portion of the third opening formed to expose at least a first portion of the second conductor, and  
a fourth opening formed by removal of at least a fourth portion of the insulator from a distal end portion of the lead body, at least a portion of the fourth opening formed to expose at least a second portion of the second conductor;  
a first conductive link within the first opening, the first conductive link electrically connected to the first conductor;  
a second conductive link within the second opening, the second conductive link electrically connected to the first conductor;  
a third conductive link within the third opening, the third conductive link electrically connected to the second conductor;  
a fourth conductive link within the fourth opening, the fourth conductive link electrically connected to the second conductor;  
a first band electrode electrically connected to the first conductive link to electrically connect the first band to the first conductor, and electrically connected to the second conductive link to electrically connect the first band to the first conductor; and  
a second band electrode electrically connected to the third conductive link to electrically connect the second band to the second conductor, and electrically connected to the fourth conductive link to electrically connect the second band to the second conductor.

76. The medical lead in accordance with Claim 75 wherein the first conductor and the second conductor extend substantially the length of the lead body and are spirally wound about a longitudinal axis of the lead body.

77. The medical lead in accordance with Claim 76 wherein the first conductive link and the second conductive link comprise a one of an electroplating material and a conductive epoxy.

78. The medical lead in accordance with Claim 43 further comprising a third conductor and a fourth conductor, and wherein the first conductor, the second conductor, the third conductor and the fourth conductor are each spaced about the same distance from a longitudinal axis of the body member.

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**APPENDIX B**  
**EVIDENCE APPENDIX**